

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA**I. General Information**

- A. Submitted By: ADAC Laboratories
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Milpitas, CA 95035
Tel: (408) 321-9100
Fax: (408) 321-9686
- Contact Person: Dennis Henkelman at address above
- B. Device Trade Name: 3D-MSPECT
Common Name: Gamma Camera System
Classification Name: System, Emission Computed Tomography
- C. Predicate Device: ADAC CEQUAL®
Sopha Sophy NXT
- D. Device Description:

3D-MSPECT is a software application designed to review and quantitatively analyze cardiac SPECT perfusion nuclear medicine patient studies. 3D-MSPECT operates as an independent application on the ADAC Pegasys system. The application provides tools for viewing standard and gated cardiac SPECT images on both a slice-by-slice basis and as a three-dimensional rendered image. Additionally, it provides a quantitative assessment of heart function by computing and displaying left ventricular chamber volume, ejection fraction, and transient ischemic dilation (TID) values and provides an assessment of the data set in comparison to similar patients. Physicians use this information to assess the anatomical and physiological functionality of the heart and analyze the presence of myocardial defects.

3D-MSPECT can be used to display the left ventricular endocardial and epicardial surfaces, polar maps indicating perfusion, wall thickening, wall motion, and reversibility, a 3D rendered image of the cardiac surfaces, and the

short axis, vertical long, and horizontal long slice data. These can be displayed for a single data set or as a comparison of related data sets (i.e., stress, rest, delay, or Vantage). Physicians can also use this application to create, modify and review Normals files from patient data available in the Pegasys database.

E. Indications for Use:

The ADAC 3D-MSPECT application is intended to provide processing and 3-dimensional display of reconstructed Cardiac SPECT studies.

F. Technological Comparison:

The ADAC 3D-MSPECT, ADAC CEQUAL, and Sopha Sophy NXT Cardiac Software have similar indications for use and utilize similar types of data sets for analysis, with the exception of the Vantage data sets used by 3D-MSPECT. In addition, these applications perform similar quantifications (calculations) used to produce image displays of the data sets.

II. Testing

Images were generated using a prototype of the application. The quality of the images produced was verified to be similar to the quality of images produced by the predicate devices.



JUN 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dennis W. Henkelman
Director, Regulatory Affairs and Quality Assurance
ADAC Laboratories
540 Alder Drive
Milpitas, CA 92035

Re: K980867
3D-MSPECT (Gamma Camera System)
Dated: March 5, 1998
Received: March 6, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Henkelman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: 3D-MSPECT

Sponsor Name: ADAC Laboratories

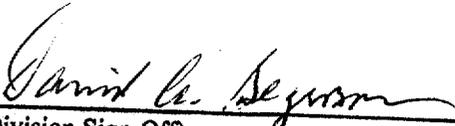
Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980867